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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,117	11/02/2007	**Philippe Cronet**	101278-1P US	3672

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	**PAPER NUMBER**
1652	
MAIL DATE	**DELIVERY MODE**
06/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,117	CRONET ET AL.	
	Examiner	Art Unit	
	DELIA M. RAMIREZ	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-21 are pending.

It is noted that two sets of claims were filed on 5/11/2006 containing 32 and 21 claims each. The set comprising 32 claims appears to be the original set of claims, and the set comprising 21 claims appears to have amended claims. Upon a cursory review of both sets of claims, it was noticed that the amended set of claims does not show the correct status identifiers for many of the claims. For example, no status identifier has been provided for claims 22-32 (canceled?), claim 2 has been identified as original when it is clear from the original set of claims that claim 2 has been amended. In the interest of advancing prosecution, the examiner contacted Ms Christine McCormack on June 8, 2009 to clarify the issue. Ms McCormack indicated that applicant's intended set of claims for examination purposes is that having 21 claims.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-2, 4-7, 9, 16, drawn in part to the polypeptide of SEQ ID NO: 17.

Group 2, claim(s) 1-9, 16, drawn in part to the polypeptide of SEQ ID NO: 18.

Group 3, claim(s) 1-9, 16, drawn in part to the polypeptide of SEQ ID NO: 19.

Group 4, claim(s) 10-14, drawn in part to a nucleic acid encoding the polypeptide of SEQ ID NO: 17, a vector, a host cell and a method to produce said polypeptide.

Group 5, claim(s) 10-14, drawn in part to a nucleic acid encoding the polypeptide of SEQ ID NO: 18, a vector, a host cell and a method to produce said polypeptide.

Group 6, claim(s) 10-14, drawn in part to a nucleic acid encoding the polypeptide of SEQ ID NO: 19, a vector, a host cell and a method to produce said polypeptide.

Group 7, claim(s) 15, drawn in part to an antibody capable of selectively binding to the polypeptide of SEQ ID NO: 17.

Group 8, claim(s) 15, drawn in part to an antibody capable of selectively binding to the polypeptide of SEQ ID NO: 18.

Group 9, claim(s) 15, drawn in part to an antibody capable of selectively binding to the polypeptide of SEQ ID NO: 19.

Group 10, claim(s) 17, drawn in part to a method of treating, preventing, managing or ameliorating the symptoms of hemorrhagic disease or disorder, wherein said method requires the administration of a composition comprising the polypeptide of SEQ ID NO: 17.

Group 11, claim(s) 17, drawn in part to a method of treating, preventing, managing or ameliorating the symptoms of hemorrhagic disease or disorder, wherein said method requires the administration of a composition comprising the polypeptide of SEQ ID NO: 18.

Group 12, claim(s) 17, drawn in part to a method of treating, preventing, managing or ameliorating the symptoms of hemorrhagic disease or disorder, wherein said method requires the administration of a composition comprising the polypeptide of SEQ ID NO: 19.

Group 13, claim(s) 18, drawn in part to a method of causing blood to clot wherein said method requires a composition comprising the polypeptide of SEQ ID NO: 17.

Group 14, claim(s) 18, drawn in part to a method of causing blood to clot wherein said method requires a composition comprising the polypeptide of SEQ ID NO: 18.

Group 15, claim(s) 18, drawn in part to a method of causing blood to clot wherein said method requires a composition comprising the polypeptide of SEQ ID NO: 19.

Group 16, claim(s) 19-20, drawn in part to a method of producing a crystal of the polypeptide of SEQ ID NO: 17 complexed to a Fab fragment.

Group 17, claim(s) 19-20, drawn in part to a method of producing a crystal of the polypeptide of SEQ ID NO: 18 complexed to a Fab fragment.

Group 18, claim(s) 19-20, drawn in part to a method of producing a crystal of the polypeptide of SEQ ID NO: 19 complexed to a Fab fragment.

Group 19, claim(s) 21, drawn in part to a crystal of the polypeptide of SEQ ID NO: 17.

Group 20, claim(s) 21, drawn in part to a crystal of the polypeptide of SEQ ID NO: 18.

Group 21, claim(s) 21, drawn in part to a crystal of the polypeptide of SEQ ID NO: 19.

2. The inventions listed as Groups 1-21 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions listed as Groups 1-21 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking Groups 1-21 is a mutant carboxypeptidase U which has a different thermal stability compared to the corresponding wild type carboxypeptidase U, which is shown by Schneider et al. (Journal of Biological Chemistry 277(2):1021-1030, 2002; cited in the IDS) to lack novelty or inventive step since Schneider et al. teach variants of TAFI (carboxypeptidase U) which have different thermal stability compared to the corresponding wild-type carboxypeptidase U including a variant which is more thermally stable (Ile at position 325; Abstract) and also teach that the region corresponding to positions 302-330 is a region which is important for thermal stability of the enzyme (page 1021, right column, last 10 lines). Thus, the technical feature does not make a contribution over the prior art and the claimed inventions do not meet the requirement of unity of invention under PCT Rule 13.2.

4. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

5. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Claim 1 link(s) inventions 1-3. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer

applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from

either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez, Ph.D., whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (571) 272-0811. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Delia M. Ramirez/

Primary Patent Examiner
Art Unit 1652

DR
June 11, 2009